

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

(Use as many shorts as necessary)

Sheet	1	of	5
-------	---	----	---

**Complete if Known**

Application Number	09/432,109
Filing Date	October 29, 1999
First Named Inventor	Jacques Paris et al.
Art Unit	1616
Examiner Name	Sabiha Qazi
Attorney Docket Number	6730/6555/JPW/AG

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initialed*	Cite No.†	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	†*
		Country Code* Number *Kind Code* (if known)				
		EP 0 136 011 B1	01-22-1997			
		EP 0 309 263	09-24-1987			
		FR 2,737,411	02-07-1997			
		FR 2,754,179	04-10-1998			

Examiner	/Sabina Qazi/
----------	---------------

Date	11/24/2008
------	------------

EXAMINER: Initial if reference considers whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See *Kinds Documents* of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Prior Office that issued the citation, by the two-letter code (WIPO Standard ST 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take about 15 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Applicants: J. Paris et al.

Serial No.: 09/423,109

ALL REFERENCES CONSIDERED EXCEPT WHERE NOTED THROUGH. /S.Q./

## Exhibit A

PTO/SB/089 (04-07)  
Approved for use through 09/30/2007. OMB 0651-0031  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2

of 5

### Complete if Known

Application Number	09/432,109
Filing Date	October 29, 1999
First Named Inventor	Jacques Paris et al.
Art Unit	1616
Examiner Name	Sabiha Qazi
Attorney Docket Number	6730/76555/JPWJAG

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Affinito et al., (1998). Ultrasonographic measurement of endometrial thickness during hormonal replacement therapy in postmenopausal... Ultrasound Obstet Gynecol, 11:343-346	
		Basdevant et al., (1991). Effects of Norgestrel Acetate (5mg/d) On Hormonal, Metabolic and Hemostatic Parameters In Premenopausal Woman. Contraception, 44(6):599-605	
		Bernard A.M. et al., (1994). Menopausal: Bone and Therapeutic Regimens (Cont). International Journal of Gynecology & Obstetrics, pp. 124	
		Birkauser M. et al. (1995). Substitution Hormonale: Une Indication Bien Posee et Des Schemas, De Traitement Individuels Sont Determinants... Med et Hyg, 53:1770-3	
		Bocanera R. et al., (1993). Effect of a HRT Regime (micronized 17-estradiol and medroxy progesterone acetate) On The... Bleeding and Endometrial Function, p.17, Abstract 40	
		Carranza-Lira, (1998). Endometrial Changes According to Hormone Replacement Therapy... Menopause: The Journal of The North American Menopause Society, 5(2):86-89	
		Doren et al., (1996). Long-term Compliance of Continuous Combined Estrogen and Progestogen... Journal of the Climacteric & Postmenopause, 25:99-105	
		Doren et al., (1997). Uterine Perfusion and Endometrial Thickness In Postmenopausal Women on Long-term... Ultrasound Obstet. Gynecol., 9:113-119	
		Doren & Scheider, (1996). The Impacts of Different HRT Regimens on Compliance. Int. J. Fertil., 41(1):29-39	
		Drapier Faure E. (1992). Le Traitement de la Menopause Evitant Les Regles: Est-il Possible? Est-il... Gynecologie, 43(4-5):271-280, including English Summary at p.271	

Examiner Signature	/Sabiha Qazi/	Date Considered	11/24/2008
--------------------	---------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.Q./

PTO/SB/088 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

of

5

**Complete if Known**

Application Number	09/432,109
Filing Date	October 29, 1999
First Named Inventor	Jacques Paris et al.
Art Unit	1616
Examiner Name	Sabiha Qazi
Attorney Docket Number	6730/76555/JPW/AG

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Eiken et al., (1996). Effects of 10 Years' Hormone Replacement Therapy on Bone Mineral Content in Postmenopausal Women. Bone, 19(5):191S-193S	
		Eiken et al., (1997). Effect on Bone Mass After Eight Years of Hormonal Replacement Therapy. British Journal of Obstetrics and Gynaecology, 104:702-707	
		Eiken and Kolthoff, (1995). Compliance With Long-Term Oral Hormonal Replacement Therapy. Maturitas, 22:97-103	
		Ettinger et al., (1998). Comparison of Continuation of Postmenopausal Hormone Replacement... Menopause: The Journal of The North American Menopause Society, 5(3):152-156	
		Fox H. et al., (1993). Six months Endometrial Histology data on Continuous Estradiol combined... Bleeding and Endometrial Function, p.40, Abstract 119	
		Hargrove J.T. et al., (1989). Menopausal Hormone Replacement Therapy With Continuous Daily Oral Micronized Estradiol and Progesterone. Obstetrics & Gynecology, 73:606-612	
		Hart et al., (1998). Long-Term Effects of Continuous Combined HRT on Bone Turnover and Lipid Metabolism in Postmenopausal Women. Osteoporosis Int., 8:326-332	
		Kuhl, (1996). Comparative Pharmacology of Newer Progestogens. Drugs, 51(2):188-215	
		Muzanuma et al., (1997). Prevention of Postmenopausal Bone Loss With Minimal Uterine Bleeding Using... Maturitas, 27:69-76	
		Neumann, (1977). Probleme der Dosisfindung:Sexualhormone. Drug Res., pp. 296-318, including English Summary at p.296	

Examiner  
Signature

/Sabiha Qazi/

Date

Considered

11/24/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.Q./

PTO/SB/08B (04-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Application Number</b>	09/432,109
		<b>Filing Date</b>	October 29, 1999
		<b>First Named Inventor</b>	Jacques Paris et al.
		<b>Art Unit</b>	1616
		<b>Examiner Name</b>	Sabiha Qazi
<b>Sheet</b> 4	of 5	<b>Attorney Docket Number</b>	6730/76555/JPW/AG

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Oettel et al., (1999). The Preclinical and Clinical Profile of Dienogest: A Short Overview. <i>Drugs of Today</i> , 35:3-12	
		Paterson et al., (1980). Endometrial disease after treatment with oestrogens and progestogens in the climacteric. <i>British Medical Journal</i> , pp. 822-824	
		Piegasa et al., (1997). Endometrial status in post-menopausal woman on long-term continuous combined hormone... <i>European Journal of Obstetrics &amp; Gynecology</i> , 72:175-180	
		Rauch and Taubert, (1993). Continuous hormone replacement therapy with estradiol valerate and chlormadinone acetate in adjectable dosages. <i>Maturitas</i> , 17:123-127	
		Recker et al., (1999). The Effect of Low-Dose Continuous Estrogen and Progesterine Therapy with Calcium and Vitamin D Bone in Elderly Women. <i>Ann Intern Med.</i> , 130:897-904	
		Reubinoff et al., (1995). Effects of hormone replacement therapy on weight, body, composition,... <i>Fertility and Sterility</i> , 64(5):963-968	
		Stadberg et al., (1996). 17B-estradiol and norethisterone acetate in low doses as continuous combined hormone replacement therapy. <i>Maturitas</i> , 23:31-39	
		Thomas et al., (1993). Postmenopausal Hormone Therapy. 7th Intern. Cong. on the Menopause, Stockholm, Abstract No. 372	
		Ulrich et al., (1997). Quality of life and patient preference for sequential versus continuous... <i>International Journal of Gynecology &amp; Obstetrics</i> , 59:S11-S17	
		Whitehead et al., (1982). Effects of Various Types and Dosages of Progestogens on the Postmenopausal Endometrium. <i>The Journal of Reproductive Medicine</i> , 27(8):539-548	

<b>Examiner Signature</b>	/Sabiha Qazi/	<b>Date Considered</b>	11/24/2008
---------------------------	---------------	------------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

(Use as many sheets as necessary)

**Complete if Known**

<b>Application Number</b>	09/432,109
<b>Filing Date</b>	October 29, 1999
<b>First Named Inventor</b>	Jacques Paris et al.
<b>Art Unit</b>	1616
<b>Examiner Name</b>	Sabiha Qazi
<b>Attorney Docket Number</b>	6730/76555/JPW/AG

Sheet	5	of	5
-------	---	----	---

[illegible]

Examiner Signature	/Sabiha Qazi/	Date Considered	11/24/2008
-----------------------	---------------	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

This collection of information is required by 37 CFR 1.918. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.Q./